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|---|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/645,962  | 08/22/2003    | David Farrar         | PT-2683-US-NP       | 8400             |
| 99818   | 7590          | 03/07/2011           | EXAMINER            |                  |
| Osha Liang LLP, Smith & Nephew, Inc.<br>150 Minuteman Road<br>Andover, MA 01810 |               |                      | STROUD, JONATHAN R  |                  |
| ART UNIT  | PAPER NUMBER  |                      |                     |                  |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |
|------------------------------|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/645,962 | <b>Applicant(s)</b><br>FARRAR ET AL. |
|                              | <b>Examiner</b><br>JONATHAN STROUD   | <b>Art Unit</b><br>3774              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 05/26/2010.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 58-83 is/are pending in the application.
- 4a) Of the above claim(s) 61, 64, 65, 70, 77-83 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 58-60, 62, 63, 66-69 and 71-76 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Crafterperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 05/26/2010
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/26/2010 has been entered.

As an initial matter, the claim amendments of 05/26/2010 will be entered and claims 58–76 appear to be drawn to subject matter generically within the scope of the claims previously presented by applicant.

### *Election/Restrictions*

In response to applicant's addition of new claims directed toward a separate class of invention, applicant's attention is drawn to MPEP 819 [R-3] and the following:

#### **819 [R-3] Office Generally Does Not Permit Shift**

The general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and action given on the elected subject matter. Note that the applicant cannot, as a matter of right, file a request for continued examination (RCE) to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined (i.e., applicant cannot switch inventions by way of an RCE as a matter of right). When claims are presented which the examiner holds are drawn to an invention other than the one elected, he or she should treat the claims as outlined in MPEP § 821.03.

#### **821.03 [R-3]**

#### **Claims for Different Invention Added After an Office Action**

Claims added by amendment following action by the examiner, MPEP § 818.01, § 818.02(a), to an invention other than previously claimed, should be treated as indicated by 37 CFR 1.145.

37 CFR 1.145.

**Subsequent presentation of claims for different invention.**

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144. The action should include form paragraph 8.04.

Newly submitted claims 77–83 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: They are drawn to a method of manufacture of a ceramic device, properly classifiable in class 264, subclass 5.

Further, in the Election Restriction filed 09/19/2005, applicant had elected the species directed to a medical device with a first component comprising a ceramic component and a second component comprising a polymer. As such, claims 61, 64, 65 (first component comprising a polymer), and 70 are also constructively elected by original presentation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 61, 64, 65, 70, and 77–83 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 58-60, 62, 63, 66-69 and 71–76 will be addressed on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 59 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Re claim 59, applicant's specification supports and states "pore size of about 20-2000 microns," not "about 20 to 2000 microns."

Re claim 60, a similar issue exists.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims read "pore size of about 20 to 2000 microns." It is unclear if that claim reads on "about 20" to "about 2000 microns" or to about "20 to 2000 microns." The interpretation is significant as applicant may not have written description support in the specification for some of these values. Appropriate clarification is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 58–60, 62, 63, 66 and 69–76 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Publication to King et al, 2004/0002770.**

Re claim 58, King discloses a polymer-bioceramic structure used to repair bone defects, which comprise a polymer disposed in a porous bioceramic matrix.

Re claim 59, the pore size is about 100 to about 1000 microns.

Re claim 60, King discloses that the void volume should be about 80, 50, or 70 of volume, para. 0013; likewise King discloses using a commercially available scaffold that has a porosity of 90%, para. 0027. *See also* para. 0037 ("interstices, pockets, channels, passages, tunnels, and the like comprise less than 50% of the volume possessed by the porous bioceramic matrix.")

Re claim 62, King discloses a first bioceramic component.

Re claim 63, King discloses the other component can be a strengthening polymer material.

Re claim 66, King discloses a first component is a bioceramic and a second is a polymer.

Re claim 69, King discloses filling the structure with bioactive substances or drugs, abstract.

Re claim 70, King discloses bioresorbable polymers, para. 0012, 0028.

Re claim 71, King discloses collagen, para. 0032

Re claim 72, King discloses glycolides, para. 0029.

Re claim 73, King discloses block copolymers made of blends of glycolic acid and trimethylene carbonate, i.e., Polyglyconate B (aka Maxon TM), *see* claim 15, and further discloses using tricalcium phosphate as the bioceramic material, para. 0010.

Re claim 74, King disclose polylactic acid (PLA), para. 0010, and hydroxyapatite, para. 0023.

Re claim 75, King discloses monomers forming the polymers.

Re claim 76, King discloses monomers such as cyclic esters, para. 0031.

**Claims 58–60, 62–63, 66, 70–74 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent to Beam *et al* 7,122,057.**

Re claim 58, Beam discloses creating a porous pre-formed "engineered regenerative biostructure" (erb) for implantation into a human body as a bone substitute, and discloses it be porous, abstract.

Beam further discloses filling the interstitial porous places with a polymer material, "infused as a monomer and then polymerized," col. 21 ll. 65-68; *see also* col.

22 II. 10-20 ("The final biostructure could have essentially all of its empty spaces filled, or it could still have empty spaces.")

Re claim 59, for varying pore sizes see fig. 22.

Re claim 60, likewise, Beam discloses the entire range of pore sizes disclosed in fig. 22 which correspond to a wide range of interstitial volumes.

Re claim 62, as just explained, Beam discloses a first ceramic material and a polymer filler material.

Re claim 63, Beam discloses the other component can be a strengthening polymer material, as explained above.

Re claim 66, Beam discloses the first component is ceramic and the second polymer.

Re claim 69, Beam discloses filling the structure with "bioactive substances," col. 22 II. 5-20.

Re claim 70, Beam discloses the polymers (as follows) are bioabsorbable.

Re claim 71, Beam discloses polymers in the genus at Col. 18 II. 65-68, col. 19 II. 1.

Re claim 72, Beam discloses polymers in the genus at Col. 18 II. 25-35.

Re claims 73 and 74, Beam discloses hydroxyapatite and tricalcium phosphate, col. 18 II. 20-22, and glycolic acid, trimethylene carbonate, and polylactic acid, see cols. 18 & 19, II. 55-68 & 1-35.

1. **Claims 58-60, 62, 66, 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown 2003/0003127.**

Re claim 58, Brown teaches a unitary perform device, 10, made up of a composite scaffold of a first porous ceramic phase base, abstract, and a second porous polymer phase, abstract. Brown teaches that the polymer phase infiltrates the macropores of the ceramic phase, para. 0026, forming a solid interlocking perform structure. As such, it is substantially non-porous prior to implantation into a patient, where the second component has a higher rate of in vivo degradation.

Further, Brown teaches that a ceramic that is free of micropores and has macropores that are filled by polymer phase, 0026, and a polymer phase that has only micropores, so that the final ceramic/polymer base is "substantially" non-porous.

Re claim 59, Brown discloses pore sizes in the range of 25 to 600 microns, para. 0028.

Re claim 60, Brown discloses a range of porosities franging from about 20 to about 98 percent, para. 0024.

Re claim 62, as stated above, one of the first and second components comprises a ceramic.

Re claim 66, as stated above, the first component is ceramic and the second is polymer.

Re claim 69, Brown discloses a therapeutic additive, para. 0058.

Re claim 70, Brown discloses the polymers (as follows) are bioabsorbable.

Re claim 71, Brown discloses polyorthoesters, para. 0010.

Re claim 72, Brown discloses a polyglycolide, para. 0010.

Re claim 73, Brown discloses tricalcium phosphate, see claim 13 of Beam; Beam discloses glyolic acid and trimethylene carbonate and copolymers, claims 16 and 17 of Beam.

Re claim 74, Brown discloses hydroxyapatite, see claim 13 of Beam; Beam discloses polylactic acid, claim 16 of Beam.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**2. Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication to King *et al*, 2004/0002770, or to Brown 2003/0003127, or to Beam *et al* 7,122,057.**

Re claims 67 and 68, the rate of degradation is disclosed (in King) is a results-effective variable and would be advantageously altered.

It is contemplated that ***the rate of biodegradation, bioerosion, or bioresorption of the polymer component of the structures described herein***, or the rate of release of bioactive agents incorporated in the structures described herein ***may be controlled by varying either the type of or molecular weight of the polymer or copolymer components***, by including a release rate modification agent, or by varying the combination and concentrations of ingredients that comprise the polymer itself.

. . . In certain embodiments, it is appreciated that a perimeter that resorbs rapidly and allows rapid infiltration of bone ingrowth at the perimeter relative to the interior ***may be desirable***.

Para. 0034–35; 0037.

Further, King, Beam, and Brown all disclose numerous polymers and ceramics with varying rates of degradation and selecting them based on varying the rates in degradation; and various combinations which would fall well within the ranges disclosed.

The optimization within prior art conditions is obvious to one of ordinary skill in the art. See MPEP 2144.05. Further, the selection of a material or equivalent recognized in the prior art supports a *prima facie* case of obviousness. See MPEP 2144.05 II.A.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the choices of materials laid out in King, Brown, or Beam, or to select some of the material combinations disclosed, which would produce differentials in degradation within the ranges disclosed, and also because King teaches those are results-effective variables which are well within one of ordinary skill in the arts' skill to optimize. See MPEP 2144.05 II.A.

### ***Conclusion***

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN STROUD whose telephone number is (571)270-3070. The examiner can normally be reached on 8-4, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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